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REMARKS

In the above-identified Office Action, Examiner Reimers repeated her prior arguments concerning the patentability of the pending claims, and offered a response to some of the comments on patentability previously made by the Applicant. The Examiner is respectfully requested to reconsider her positions in light of the following.

Claims 1-37 are pending, with claims 8, 12 and 17 withdrawn from consideration as allegedly relating to an independent and/or distinct species. Of these, claims 1, 36 and 37 are independent. Respectfully, the Office Actions in this case have not met their burden of proving that each of these claims, and others, are unpatentable over the relied-on references.

Turning first to claim 1, it recites a surgical tether having at least (1) a cord with a tensile strength sufficient to maintain a desired distance or orientation of the two bone portions, (2) a sheath substantially encasing the cord that has a plurality of fibers and provides an abrasion resistant coating to the cord, and (3) a radiopaque element. A second sheath that substantially encases the first sheath may also be provided.

The Office Action has not met its burden of proving that the Dunn reference anticipates claim 1. It is axiomatic that, to anticipate, a reference must show all elements of the claim arranged as recited in the claim. As MPEP 2173.05(g) specifies, this includes features claimed in functional terms (“[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used”).

Page 2 of the Office Action argues that item 30 of Dunn is a “cord” as in claim 1, and that item 20 is the recited “sheath.” Thus, item 30 must be explicitly or inherently disclosed in

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Dunn to have a tensile strength sufficient to maintain a desired distance or orientation of two bone portions, since that structural characteristic is recited in the claim. Nothing in Dunn suggests that feature, since the only disclosure in Dunn concerning item 30 is at column 5, lines 5-18, and it merely states that item 30 "provide[s] shape" for item 20 and identifies a biocompatible elastomer for its composition. The "sufficient tensile strength" feature does not necessarily follow from that minimal disclosure, and therefore cannot be inherent in the Dunn reference either. Considering also that Dunn specifically calls its item 20 a "load-bearing member" (see, e.g., column 3, line 47-48), telling the person of ordinary skill that item 20 is the thing that holds tissues, it is not possible to conclude that Dunn's item 30 is a cord having the structural tensile strength feature recited in claim 1.

While page 7 of the Office Action included comments directed at item 30 of Dunn, respectfully those comments do not rebut the above-stated facts. Lines 4 and 5 of page 7 repeat the claim language and attribute it to item 30, but no evidence or persuasive reasoning is provided to substantiate that conclusion. The portions of the abstract and columns 2, 6 and 7 of Dunn that were listed on page 7 do not refer to item 30, but instead refer to the "load-bearing" item 20. Moreover, it is incorrect to suggest that the "tensile strength" language in claim 1 is an "intended use." "Tensile strength" in the indicated amount is very clearly a structural attribute of the recited cord. The Office Action also has not provided any evidence or chain of reasoning to support any allegation that the Dunn reference can perform a particular "intended use." In other words, even if it is true that where a prior art device can meet an intended use it anticipates that portion of a claim, in this case there has been no sufficient showing that the Dunn device can, in fact, meet an alleged "intended use."

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Turning to the "sheath" part of claim 1, the claim recites that the sheath provides an abrasion resistant coating to the cord. Dunn does not disclose, explicitly or inherently, that its item 20 provides an abrasion resistant coating. Rather, it plainly relies on an extra outer layer 40 of 1/16 inch thickness and friction fit onto item 20 to "withstand" abrasion (see column 4, lines 48-54). Thus, Dunn discloses to the person of skill in the art not that item 20 gives abrasion resistance to item 30, but that an extra layer is required to withstand abrasion. Consequently, item 20 of Dunn cannot meet all features of the "sheath" of claim 1.

Once again, the comments in the Office Action on page 7 do not sufficiently address this lack. The abrasion resistant coating is plainly a structural feature of the recited sheath, and no showing has been or can be made that Dunn's item 20 is or can be an abrasion resistant coating. The Office Action's comments also suggest that Applicant "relies" on features in the specification in showing the patentability of claim 1, but respectfully that is not the case. The claimed sheath provides the recited coating, and those features cannot be gleaned from Dunn by one of ordinary skill in this art. The specification provides a reason for those features, and it is notable that the Dunn reference does not.

The Office Action also realleged that the combination of the Poirier reference and the Dunn reference renders independent claim 1 obvious. However, the combination does not show all features of claim 1, and the Poirier reference teaches away from the combination proposed by the Examiner. As previously pointed out, claim 1 recites a sheath that provides an abrasion resistant coating to an inner cord, and the Office Action asserts that item 12 of Poirier is a "cord" and item 16 is a "sheath." The Office Action asserts that item 16 provides the recited coating, but gives no evidence, reasoning, or other explanation of how it reached that conclusion. There

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is no explicit or inherent disclosure of item 16 providing abrasion resistance, and there is no reason apparent from the reference for it to do so, since another layer is over item 16. Moreover, Poirier explains that its structure operates like a "Chinese finger-trap," relying on friction to lock together adjacent layers. One of ordinary skill would understand from that disclosure that item 16 is not an "abrasion resistant coating" because of Poirier's need for frictional joining. Thus, not only is the burden of proving unpatentability not met, but the Poirier reference understood as a whole does not show a sheath that provides an abrasion resistant coating.

The Office Action recognizes that Poirier does not disclose a radiopaque element nor bone fasteners. One of ordinary skill would not believe it obvious to import those items from Dunn to Poirier because Poirier teaches against those modifications. Poirier teaches that all of its layers should break simultaneously so as to provide maximum strength (column 2, lines 34-36). Making one portion of the Poirier cord of a different material, e.g. a radiopaque material, rather than of one material (e.g. nylon as taught by Poirier), will defeat or at least make much more difficult that goal of simultaneous breakage taught by Poirier.

The use of screws as shown in Dunn also runs against Poirier's teachings. If such screws are inserted through the Poirier cord, the ability of the cord to operate as a "Chinese finger-trap" as taught is impaired by the screw's separation of and damage to the fibers in the respective parts. In the Dunn reference, of course, the screws are placed through eyelets formed in part of the Dunn ligament. Creating such eyelets in the Poirier cord, as taught in Dunn, requires the Poirier outer layers to be peeled back or drawn away from an inner braid, and that inner braid is woven into itself. The several layers of Poirier cannot each be woven into each other. The Poirier cord, on the contrary, is intended to have each of its layers extend along the entirety of

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the ones under it, so that the strength and simultaneous breaking qualities taught by Poirier are not compromised. Introducing the screw-related disclosure from Dunn into Poirier would not be considered obvious by one of ordinary skill because it would defeat Poirier's goals and would change its operative principles.

For at least these reasons, a showing of unpatentability of claim 1 over Dunn by itself, or over the Poirier reference combined with Dunn, has not and cannot be made. Dependent claims 2-35 are allowable at least because of their dependence from claim 1. In a prior response in this case, it was pointed out that these dependent claims may be allowable on their own merit as well. As examples, it was shown that claims 2, 3 and 14 were not anticipated by the Dunn reference nor obvious over the Poirier and Dunn references. Those remarks were not rebutted by any evidence or reasoning in the present Office Action. The Dunn reference does not disclose the radiopaque element or filament as recited in claims 11-13 as well. Accordingly, it is respectfully requested that the dependent claims be reconsidered and passed to issue as well.

Claim 27 was again rejected over a combination of the Dunn reference and the Hlavacek reference. As discussed in the previous response, Dunn teaches away from using bioabsorbable materials because its ligament is a permanent replacement for a natural ligament. See e.g. Abstract; column 1, lines 6-8; column 2, lines 20-30, 33-39, 50; column 3, lines 44-46. A bioabsorbable material is, by definition, not "permanent." Page 9 of the comments in the present Office Action offer some additional remarks concerning claim 27. It is agreed that the claim recites a biodegradable material in a "comprising" claim, as the Examiner stated. However, that is irrelevant to the point that the Dunn reference teaches permanence, and the biodegradable material of Hlavacek impairs such permanence. If Dunn's item 30 includes some measure of

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biodegradable material, it will lose some or all of its ability to provide shape to the load-bearing item 20 as the material degrades. If Dunn's item 20 includes biodegradable material, its ability to bear a load and/or be held by screws will diminish as the material degrades. The permanent replacement characteristic of the Dunn ligament would be negatively affected by introduction of a biodegradable material. Accordingly, one of ordinary skill would not be motivated to modify the Dunn reference with the Hlavacek reference as suggested in the Office Action.

With respect to independent claims 36 and 37, each includes features of claim 1 that are not present in the relied-on references, as discussed above. Claim 36 also includes a "means-plus-function" element that was not addressed in the Office Action. To reject this claim, the Examiner must find an element in the relied-on art that (A) performs the function specified in the claim, (B) is not excluded by any explicit definition in the specification for an equivalent, and (C) is an equivalent of the means-plus-function limitation, and she must provide an explanation and rationale as to why the element is an equivalent. See MPEP 2183. The interpretation of the "means" element must focus on the structure in the specification for performing the stated function and equivalents. See MPEP 2182. The Office Action did not analyze the "means" feature of claim 36 at all, and it did not provide the required explanation and rationale as to why some portion of Dunn and/or Poirier is an equivalent of that feature. For this additional reason, a sufficient case of anticipation or obviousness of claim 36 has not been made.

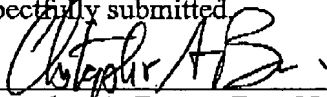
Claim 37 also includes a "means" element that was not addressed in the Office Action. In addition, claim 37 recites a radiopaque filament engaged with either the cord or the first sheath. That language makes clear that the recited filament is not the cord or the first sheath, but is engaged with one of them. The Office Action asserted that Dunn discloses "radiopaque

filaments spirally wound around at least one of the cord, the first sheath or the second sheath" (pages 2-3 of the Office Action), but did not specify where in Dunn that disclosure was found. The only references to radiopaque materials found in Dunn refers to the material of which item 30 is made. No separate radiopaque filament that is wound around items 20 or 30 of Dunn, or any other part of the reference, is disclosed in Dunn. As noted above Poirier teaches away from introducing non-uniform parts into its cord so as to maintain simultaneous breakage of all parts.

To summarize, the Examiner is respectfully requested to reconsider and withdraw the present rejections of the pending claims on at least the bases given above. The above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but are simply provided to address the rejections made in the Office Action in the most expedient fashion. Applicant reserves the right to later contest positions taken in the Office Action that are not specifically addressed herein. Further, no limitation of the claims is intended by any of the remarks herein. The claims are intended to have the full scope to which their language entitles them, including equivalents.

In conclusion, reconsideration and withdrawal of the rejections of the claims based on the remarks presented is respectfully requested. The undersigned attorney invites Examiner Reimers to call to discuss any further issues that may remain.

Respectfully submitted,



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